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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,521	11/01/2001	Timothy Samuel Girton	760-35 CIP	6660

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EXAMINER	
PATTERSON, MARC A	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,521	GIRTON ET AL.	
	Examiner	Art Unit	
	Marc A. Patterson	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,21,22 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,21,22 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

WITHDRAWN REJECTIONS

1. The 35 U.S.C. 102(b) rejection of Claim 26 as being anticipated by Yen et al (U.S. Patent No. 4,906,377) as evidenced by Verona et al (U.S. Patent No 5,776,185).

NEW REJECTIONS

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yen et al (U.S. Patent No. 4,906,377) in view of Verona et al (U.S. Patent No 5,776,185) and Kidd et al (U.S. Patent No. 6,770,202 B1).

With regard to Claim 26, Yen et al disclose a PTFE (comprising polytetrafluoroethylene; column 3, lines 11 – 16) membrane (column 4, line 37) having a polymeric component which is incompatible with the PTFE in the form of a liquid (an oligomer, therefore a liquid, which is phase separated, therefore comprising discrete domains which are incompatible; column 4, lines 14 – 15) which is extractable therefrom to create pores in the resin (the solvent of the oligomer is extracted and the resulting polymer is microporous; column 2, lines 41 – 45). Yen et al do not disclose a node and fibril structure or expansion, and a non – expanded tube having PTFE resin having no node and fibril structure is therefore disclosed by Yen et al; Yen et al disclose pores

which have a diameter of 5 microns (column 4, lines 14 – 16) and therefore permit tissue ingrowth. Yen et al do not disclose an extrudate which permits tissue growth upon implantation, but Verona et al disclose that PTFE is biocompatible (column 4, lines 25 – 27); the property of permitting tissue growth upon implantation is therefore inherent to Yen et al; the membrane is extruded in the form of a sheet (column 4, line 27). Yen et al fail to disclose a membrane which is extruded in the form of a tube.

Kidd et al teaches the interchangeable extrusion of a membrane (column 4, line 3) comprising PTFE (comprising tetrafluoroethylene monomer; column 2, lines 48 – 50) in the form of a sheet or tube (column 4, lines 4 – 6) for the purpose of obtaining a membrane which is flexible (column 7, line 23). One of ordinary skill in the art would therefore have recognized the advantage of providing for the extrusion in the form of a tube of Kidd et al in Yen et al, which a membrane, depending on the flexibility of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a membrane which is extruded in the form of a tube in Yen et al in order to obtain a membrane which is flexible as taught by Kidd et al.

4. Claims 1 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabasso et al (U.S. Patent No. 4,951,381) in view of Kidd et al (U.S. Patent No. 6,770,202 B1).

With regard to Claim 1, Cabasso et al disclose a medical device (used for slow release of drugs; column 6, lines 7 – 8) PTFE (column 5, line 11) which is implantable (biodegradable; column 6, lines 9 – 10) and comprises a PTFE matrix (polytetrafluoroethylene; column 5, lines 5 – 11) having therein a polymeric material (water soluble polymer; column 4, lines 59 – 60)

which is solid (gelatin; column 4, line 60) which is extractable upon exposure to dissolving medium to create pores in the matrix (removal of the components yields a beehive morphology comprising holes which are pores; column 5, lines 60 – 68; column 6, lines 1 – 4) and therefore form discrete domains; the pores have a diameter of 10 micrometers (column 6, lines 7 – 10) and therefore permit tissue growth upon implantation; the extractable polymeric material disclosed by Cabasso et al is enveloped by a crosslinked polymer shell (column 5, lines 60 – 68) and Cabasso et al therefore disclose an interpenetrating network comprising PTFE. Cabasso et al do not disclose a PTFE matrix having a node and fibril structure and do not disclose expansion, and Cabasso et al therefore disclose a non expanded PTFE matrix having no node and fibril structure. The device is a membrane (column 3, lines 54 – 55) and which is made by casting from a solvent (column 2, lines 54 – 58) Cabasso et al fail to disclose a matrix which is extruded into a tube.

Kidd et al teaches the interchangeability of solution casting or extrusion in the form of a tube (column 4, lines 4 – 6) of a membrane (column 4, line 3) comprising PTFE (comprising tetrafluoroethylene monomer; column 2, lines 48 – 50) for the purpose of obtaining a membrane which is flexible (column 7, line 23). One of ordinary skill in the art would therefore have recognized the advantage of providing for the extrusion in the form of a tube of Kidd et al in Yen et al, which a membrane, depending on the flexibility of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a membrane which is extruded in the form of a tube in Cabasso et al in order to obtain a membrane which is flexible as taught by Kidd et al.

With regard to Claim 21, the polymeric material disclosed by Cabasso et al comprises silicone (polyamino methylsiloxane; column 4, lines 60 – 62).

5. Claims 2 – 3, 22 and 24 – 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabasso et al (U.S. Patent No. 4,954,381) in view of Kidd et al (U.S. Patent No. 6,770,202 B1) and further in view of Chuter (U.S. Patent No. 6,293,969)

Cabasso et al and Kidd et al disclose a medical device comprising a PTFE membrane comprising extractable polymeric material as discussed above. With regard to Claim 2, Cabasso et al and Kidd et al fail to disclose a radially distensible stent positioned axially about the tubular extrudate.

Chuter teaches a PTFE membrane (PTFE membrane material; column 2, lines 49– 53) comprised in first and second stents (first and second stent graft components; column 2, lines 45 – 47) with one stent positioned about the other stent (the stent components are at different levels, one below the other; column 2, lines 28 – 29) for the purpose of obtaining a stent which is biologically inert (column 2, lines 49 – 53). One of ordinary skill in the art would therefore have recognized the advantage of providing for the stent of Chuter in Cabasso et al and Kidd et al, which a PTFE membrane, depending on the desired inertness of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a stent, therefore radially distensible, positioned axially about the tubular extrudate in Cabasso et al and Kidd et al in order to obtain a stent which is biologically inert as taught by Chuter.

With regard to Claim 3, the stent disclosed by Chuter is a vascular graft (stent – graft for an artery; column 1, lines 39 – 45).

With regard to Claim 22, the extractable material disclosed by Cabasso et al is particulate (droplets; column 4, lines 50 – 55) and having a particle size of 5 microns (0.1 – 3000 micrometers; column 2, lines 58 – 59).

With regard to Claim 24, Cabasso et al and Kidd et al do not disclose a component other than the PTFE and extractable polymeric material; Cabasso et al and Yen et al therefore disclose a device consisting essentially of a PTFE resin and a polymeric component.

With regard to Claim 25, the extractable polymeric material disclosed by Cabasso et al and Kidd et al comprises polymethylmethacrylate (polyhydroxyethylmethylacrylate and the like; column 4, lines 63 – 64).

ANSWERS TO APPLICANT'S ARGUMENTS

6. Applicant's arguments regarding the 35 U.S.C. 102(b) rejection of Claim 26 as being anticipated by Yen et al (U.S. Patent No. 4,906,377) as evidenced by Verona et al (U.S. Patent No 5,776,185), 35 U.S.C. 103(a) rejection of Claims 1 and 21 as being unpatentable over Cabasso et al (U.S. Patent No. 4,951,381) in view of Yen et al (U.S. Patent No. 4,906,377), 35 U.S.C. 103(a) of Claims 2 – 3, 22 and 24 – 25 as being unpatentable over Cabasso et al (U.S. Patent No. 4,951,381) in view of Yen et al (U.S. Patent No. 4,906,377) and further in view of Chuter (U.S. Patent No. 6,293,969), of record in the previous Action, have been carefully considered but have not been found to be persuasive for the reasons set forth below.

Applicant argues, on page 7 of the remarks dated March 6, 2006, that Yen et al disclose a copolymer of polytetrafluoroethylene, but Yen et al do not disclose PTFE, which is not a copolymer.

However, because the claims are limited to PTFE homopolymer, and it is not clear that there is any support for this limitation in the specification, and polytetrafluoroethylene is PTFE, PTFE is disclosed by Yen et al.

Applicant also argues, on page 8, that Cabasso et al do not disclose extractable material in a solid form.

However, extractable material 'in a solid form' is not claimed; furthermore, Cabasso et al disclose extractable material comprising gelatin, which is a solid polymer in nature.

Applicant also argues, on page 10, that Claim 24, unlike Cabasso et al, is an intermediate.

However, an intermediate is not claimed.

Applicant also argues, on page 10, that Cabasso et al do not disclose the 'consisting essentially of' language of Claim 24 because Cabasso et al disclose a copolymer, rather than PTFE.

However, as stated above, because the claims are limited to PTFE homopolymer, and it is not clear that there is any support for this limitation in the specification, and polytetrafluoroethylene is PTFE, PTFE is disclosed by Yen et al.

Applicant also argues on page 10 that the intermediate product of Cabasso et al includes solvents.

However, as stated above, an intermediate is not claimed.

Applicant also argues on page 10 that because components 'A' and 'B' of Cabasso et al react to form a copolymer, Cabasso et al does not form discrete domains which are separate and distinct.

However, Cabasso et al is not limited to an embodiment in which a copolymer is formed; furthermore, the components of Cabasso et al do not react completely; the reaction is only interfacial (column 4, lines 50 – 51) and separate, distinct components are therefore present.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc A Patterson whose telephone number is 571-272-1497. The examiner can normally be reached on Mon - Fri 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc Patterson 5/15/06
Marc A. Patterson, PhD.
Primary Examiner
Art Unit 1772